

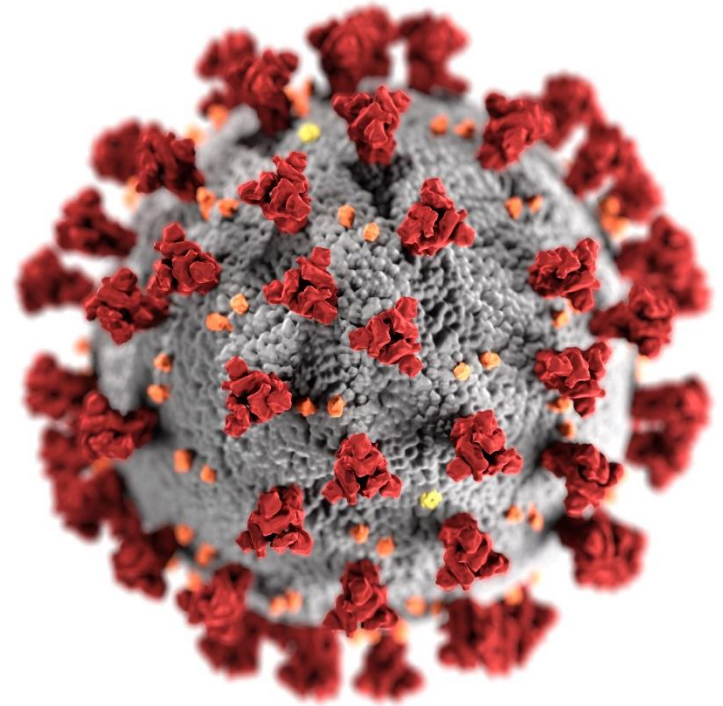
# Interim Clinical Considerations for Novavax COVID-19 Vaccine

**Elisha Hall, PhD**

**Clinical Guidelines Lead**

Advisory Committee on Immunization Practices  
Meeting

July 19, 2022



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

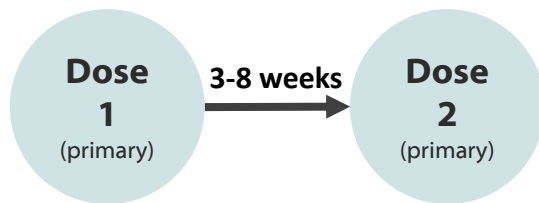
# Novavax COVID-19 Vaccination Schedule

People who are **NOT** moderately or severely immunocompromised

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**Novavax**  
(18 years and  
older)

## Primary Series

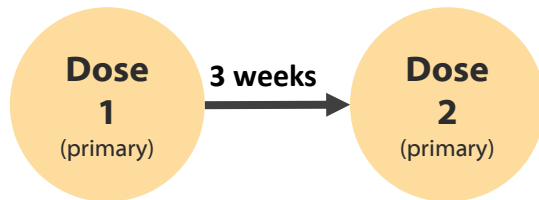


People who **ARE** moderately or severely immunocompromised

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**Novavax**  
(18 years and  
older)

## Primary Series



# Doses NOT Currently Authorized

- For people receiving a Novavax COVID-19 Vaccine primary series, the following are **NOT** currently authorized:
  - Third primary dose for people who are moderately or severely immunocompromised
  - Booster dose using ANY COVID-19 vaccine after a Novavax primary series
- CDC provides clinical guidance for what FDA authorizes; **once authorized**, these doses can be added to the COVID-19 vaccination schedule

# Mixed Primary Series

- The **same** vaccine product should be used for all doses in the primary series.
- There are limited data on the safety and efficacy of a mixed primary series composed of any combination of Moderna, Novavax, and Pfizer-BioNTechCOVID-19 vaccines.
- If a mixed primary series is inadvertently administered
  - The series is complete, and doses do not need to be repeated
  - This is considered an error; report to the Vaccine Adverse Event Reporting System (VAERS)

## Mixed Primary Series, Continued

- If a person starts but is unable to complete the primary series with the same COVID-19 vaccine **due to a contraindication**, any other age-appropriate COVID-19 vaccine may be administered to complete the series at a minimum interval of 4 weeks (28 days) from the last COVID-19 vaccine dose.
- This would not need to be reported to VAERS.

# Coadministration

- In general, COVID-19 vaccines may be administered without regard to timing of other vaccines.
  - ✓ Same day
  - ✓ Any time before
  - ✓ Any time after
- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for people for whom no specific contraindications exist at the time of the healthcare visit.
- There are additional considerations for orthopoxvirus vaccines.

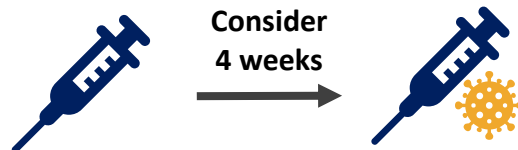
# Coadministration

- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers may consider:
  - ✓ Whether a person is behind or at risk of becoming behind on recommended vaccines
  - ✓ Likelihood of the person returning for another vaccination
  - ✓ Person's risk of becoming infected with a vaccine-preventable disease
  - ✓ Person's risk for severe disease if infected
  - ✓ Reactogenicity profile of the vaccines

# Coadministration

- Additional consideration for orthopoxvirus vaccination:

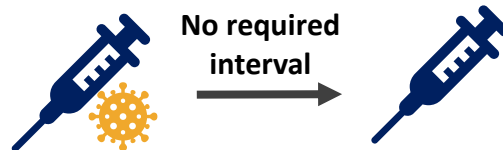
**If orthopoxvirus vaccine administered first:** Might consider waiting 4 weeks before receiving a Moderna, Novavax, or Pfizer-BioNTech vaccine



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**If Moderna, Novavax, or Pfizer-BioNTech administered first:**

No minimum interval necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak

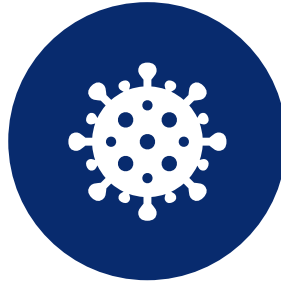




# Novavax COVID-19 Vaccine: Preparation and Administration



**Age indication:**  
18 years and older



**Dose:** 5 mcg SARS-CoV-2rS  
50 mcg Matrix-M™ adjuvant



**Injection volume:**  
0.5 mL



**Preparation:**  
Do not dilute

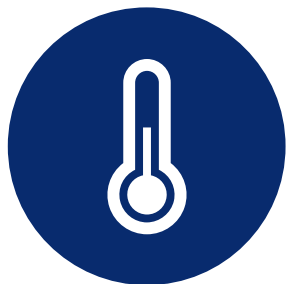


**Doses per vial:**  
10 doses



**Injection route/site:**  
Intramuscular/deltoid

# Novavax COVID-19 Vaccine: Storage



## **Storage:**

Refrigerator 2° to 8°C  
(36° to 46°F)



## **DO NOT FREEZE**



## **Beyond use time:**

6 hours after first  
puncture



## **Expiration:**

No expiration date  
is printed on the  
vial or carton

[www.NovavaxCovidVaccine.com](http://www.NovavaxCovidVaccine.com)

# Types of COVID-19 Vaccines

## mRNA

- Moderna
- Pfizer-BioNTech

## Adenovirus vector

- Janssen

## Protein subunit

- Novavax

# Contraindications & Precautions

- Contraindications
  - History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component Novavax COVID-19 Vaccine
  - History of a known diagnosed allergy to a component of Novavax COVID-19 Vaccine

# Contraindications & Precautions

- People with an allergy-related contraindication to one type of COVID-19 vaccine have a contraindication or precaution to the other type of COVID-19 vaccines
  - Contraindication: People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen
  - In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types

# Contraindications & Precautions

- Precautions
  - History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy
  - History of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose Novavax COVID-19 Vaccine
  - Moderate or severe acute illness, with or without fever
  - History of MIS-C or MIS-A
  - History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

# Myocarditis and Pericarditis

- Myocarditis or pericarditis after a dose of an mRNA or Novavax:
  - Precaution to a subsequent dose of any COVID-19 vaccine
  - Considerations for subsequent vaccination include:
    - Whether myocarditis or pericarditis was considered unrelated to mRNA or Novavax vaccination
    - Personal risk of severe acute COVID-19
    - Timing of immunomodulatory therapies
  - For people ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise using Janssen
    - People choosing Janssen should be informed of the risk of thrombosis with thrombocytopenia syndrome; the highest risk is in females ages 30–49 years

# Myocarditis and Pericarditis

- History of myocarditis or pericarditis prior to COVID-19 vaccination
  - Not a precaution
  - May receive any currently authorized or approved vaccine after the episode of myocarditis or pericarditis has resolved



## Extended Interval Between Dose 1 & 2

- No specific data on extended interval between dose 1 & 2 of Novavax
- Evidence of benefits of an extended interval in mRNA recipients
  - The small risk of myocarditis and/or pericarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses
  - Vaccine effectiveness may be increased
- Therefore an 8-week interval may be used between dose 1 & 2 to potentially reduce the risk of myocarditis and/or pericarditis

# Considerations for Extended Interval Between Dose 1 & 2

## 3-week interval

- People who are moderately or severely immunocompromised
- People ages 65 years and older
- When protection needs to be achieved soonest
  - High risk for severe disease
  - Living, working, or traveling to an area with high COVID-19 community levels

## 8-week interval

- Reduced myocarditis risk
  - Young adult males
- Optimize vaccine effectiveness

# Considerations for Extended Interval Between Dose 1 & 2

## 3-week interval

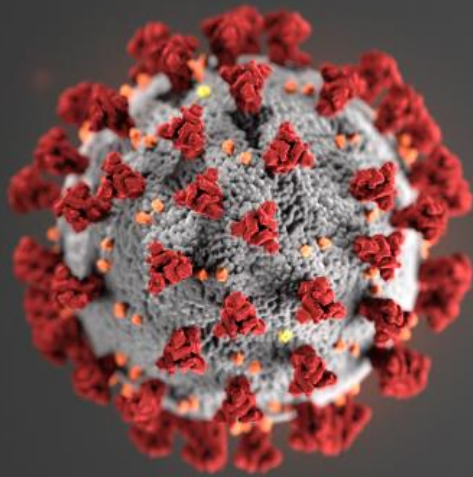
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For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

